Job Title: Quality Assurance Specialist III

List Lab's mission is to "harness bacteria's potential for a healthier world." We are a premier contract development and manufacturing organization for bacterial derived products for early clinical trials including live biotherapeutic products derived from the rapidly growing microbiome field. Live biotherapeutic products, an exciting new therapeutic, are a novel approach to disease treatment and have significant potential to improve patient lives. List Labs also specializes in the production of both native and recombinant bacterial proteins and toxins used for research and development.

List Labs offers a dynamic and congenial company environment and the convenience of working in the South Bay Area.

We are seeking a talented and motivated Quality Assurance Specialist to support our Quality and Compliance Department. This position will be primarily responsible for administering quality systems such as deviation, CAPAs, change control, vendor management, and collecting metrics data. This position will also perform GAP assessments, assist with review activities, support inspections and other duties as needed.

ESSENTIAL DUTIES AND RESPONSIBILITIES

- Maintain master hardcopy and electronic documents/records and files related to quality systems such that required documentation is retrievable and files are accurate and well organized.
- Provide QA guidance and input to deviation investigations, root cause analysis, converification of data and records to authorize closure of deviations, CAPA, and change control.
- Track and issue monthly status reports for deviations, CAPA and change control.
- Collect metrics for deviations, CAPA and change control, and external and internal audit status.
- Maintain master list of supplier audits, schedule, status and administer changes to the ASL based on supplier assessments.
- Maintain master list of audits and findings (client, internal, agency, GAP assessments) and track progress towards closure.
- Perform verification of data and records to authorize lot disposition, COO and/or COA approval.
- Work with area management to develop criteria for performing GAP assessments and developing closure plans as needed.

    - Develop tracking/status system(s) to clearly identify gaps and track through resolution.
    - Provide assistance and recommendations in the resolution of gaps.
- May assist with other related duties as defined by QA Management.

QUALIFICATION AND EXPERIENCE

- BS/BA in a scientific discipline preferably in biological sciences or related field
- A minimum of 5-8 years of relevant experience working in the quality systems aspects of Biotechnology or Pharmaceutical industry
- Direct experience in conducting documentation review/gap assessments.

KNOWLEDGE, SKILLS AND ABILITIES

- Must have excellent attention to detail and the ability to consistently meet high quality standards.
- Excellent verbal, written, and interpersonal communication skills and the ability to work collaboratively across departments.
- Must possess good organizational and time management skills. Must be systematic in obtaining and using information.
- Must be able to work independently but able to identify problems and know when to solve proactively and seek advice.
- Must be able to work under tight deadlines while delivering a high quality output.
- Strong knowledge of cGMP (e.g. FDA, EU and ICH) requirements and the ability to interpret them.
- Ability to assess compliance risks and to recommend corrections to quality system to minimize them.
- Must be proficient with computer applications (i.e. Microsoft Office products and Adobe Acrobat).